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| 10/777,041 | 02/13/2004 | Maryellen L. Giger | 248939US20 | 3848 |

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| EXAMINER |
|---|
| WOLDEMARIAM, AKILILU K |

| ART UNIT | PAPER NUMBER |
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| 2624 | |

| NOTIFICATION DATE | DELIVERY MODE |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/777,041 | GIGER ET AL. | |
| | Examiner | Art Unit | |
| | AKLILU k. WOLDEMARIAM | 2624 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *14 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,3-11,13-21 and 23-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-11,13-21 and 23-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/14/2008, 05/10/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Response to Amendment*

1. Applicant's amendment filed on January 14, 2008 has been entered. Claims 1, 3-11, 13-21 and 23-30 have been amended. Claims 2, 12 and 22 have been cancelled. Claims 1, 3-11, 13-21 and 23-30 are still pending with claims 1, 11 and 21 being an independent.

### 7.65 Affidavit or Declaration under 37 CFR 1.32: Effective to Withdraw

2. The Declaration under 37 CFR 1.132 filed January 14, 2008 is sufficient to overcome the rejection of claims 1-30 based upon Jiang et al. (US 2002/0196966a1). Jiang qualifies as prior art under 35 U.S.C 102 (a) or (e). Applicants Declarations provides an unequivocal statement that applicant conceived or invent the subject matter in Jiang as relied upon by the examiner to reject claims.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 3, 4, 6 7, 11, 13, 14, 17, 21, 23, 24, 26, 27 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Huo et al., Huo (U.S. Patent number 6, 282, 305 B1).

Regarding claim 1, *Huo discloses* a method for a computerized analysis of mammogram in digital form of a breast of a patient *(see column 9, line 60-column 10,*

*line 8, the present invention thus involves the development of a computerized method to automatically extract features that characterized mammographic parenchymal patterns and relate to breast cancer risk would potentially benefit women seeking information regarding their individual breast cancer risk),* comprising:

extracting from the mammogram at least one fractal-based feature associated with a texture of a parenchyrna of the breast *(see column 9, line 60-column 10, line 8, the present invention thus involves the development of a computerized method to automatically extract features that characterized mammographic parenchymal patterns and relate to breast cancer risk would potentially benefit women seeking information regarding their individual breast cancer risk)*;

applying the extracted said at least one fractal-based feature to at least one of a linear discriminant classifier *(see column 9, lines 48-59, In performing the comparison of extracted features with the model, at least one of linear discriminate analysis, linear regression analysis and logistic regression analysis is performed on plural extracted features)* and an artificial neural network classifier *(see column 9, lines 48-59, extracted features are merged into a measure related to the risk of acquiring cancer by applying the extracted features as inputs to a trained artificial neural network outputting a risk classification index indicative of risk of acquiring cancer)* and

determining generating a risk marker indicative of a breast disease risk for said patient a fractal characteristic of the image data based on an output of at least one of a linear discriminant classifier *(see column 9, lines 30-59, the extracted features are compared with a predetermined model based on gene carrier information and clinical*

*information, and a risk classification index is output as a result of the comparison)* and an artificial neural network classifier *(see column 9, lines 48-59, extracted features are merged into a measure related to the risk of acquiring cancer by applying the extracted features as inputs to a trained artificial neural network outputting a risk classification index indicative of risk of acquiring cancer)*.

Regarding Claim 3, *Hugo* discloses the method according to Claim 1, wherein the extracting step comprises:

extracting plural fractal-based features at multiple scales *(see column 9, line 60-column 10, line 8, selected texture measure derived form the mammograms of patient are then related to breast cancer risk via two different approaches . First, these measures were used to differentiate mammographic parenchymal patterns).*

Regarding claim 4, Hugo discloses the method according to Claim 1, wherein the extracting step comprises:

extracting plural fractal-based features from an area of a region of interest of the mammogram based on a box-counting method *(see column 11, lines 3-16, the computerized method for the assessment of breast cancer risk based on the analysis of mammographic parenchymal patterns and box-counting method is well known).*

Regarding claim 6, Huo *discloses* the method according to Claim 1, wherein the applying step comprises:

applying the features to a linear discriminant analysis classifier (*see column 9, lines 48-59, in performing the comparison of extracted features with the model, at least*

*one of linear discriminate analysis, linear regression analysis and logistic regression analysis is performed on plural extracted features).*

Regarding Claim 7, *Huo discloses* the method according to Claim 1, wherein the applying step comprises:

applying the features to an artificial neural network classifier *(see column 9, lines 48-59, extracted features are merged into a measure related to the risk of acquiring cancer by applying the extracted features as inputs to a trained artificial neural network outputting a risk classification index indicative of risk of acquiring cancer).*

Regarding Claim 10, *Huo discloses* the method according to Claim 1, wherein the extracting step comprises:

extracting from the mammogram determining a multi-fractal characteristic associated with the texture of the parenchyma of the breast *(see column 9, line 60-column 10, line 8, extract features that characterize mammographic parenchymal patterns and relate to breast cancer risk would potentially benefit women seeking information regarding their individual breast cancer risk).*

Regarding Claim 11, *Huo discloses* a system for computerized analysis of a mammogram in digital form of a breast of a patient *(see column 9, line 60-column 10, line 8, the present invention thus involves the development of a computerized method to automatically extract features that characterized mammographic parenchymal patterns and relate to breast cancer risk would potentially benefit women seeking information regarding their individual breast cancer risk)*, comprising:

a feature extraction mechanism that extracts from the mammogram at least one fractal-based feature associated with a texture of a parenchyma of the breast *(see column 9, line 60-column 10, line 8, the present invention thus involves the development of a computerized method to automatically extract features that characterized mammographic parenchymal patterns and relate to breast cancer risk would potentially benefit women seeking information regarding their individual breast cancer risk)*;

a classifier mechanism including at least one of a linear discriminant classifier *(see column 9, lines 48-59, In performing the comparison of extracted features with the model, at least one of linear discriminate analysis, linear regression analysis and logistic regression analysis is performed on plural extracted features)* and an artificial neural network classifier *(see column 9, lines 48-59, extracted features are merged into a measure related to the risk of acquiring cancer by applying the extracted features as inputs to a trained artificial neural network outputting a risk classification index indicative of risk of acquiring cancer)* and an artificial neural network to which the at least one fractal-based feature is applied *(see column 9, lines 48-59, extracted features are merged into a measure related to the risk of acquiring cancer by applying the extracted features as inputs to a trained artificial neural network outputting a risk classification index indicative of risk of acquiring cancer)*; and

risk marker generator that generates a risk marker indicative of a breast disease risk for the patient based on an output of the classifier mechanism*(see column 9, lines 30-59, the extracted features are compared with a predetermined model based*

*on gene carrier information and clinical information, and a risk classification index is output as a result of the comparison)* and an artificial neural network classifier *(see column 9, lines 48-59, extracted features are merged into a measure related to the risk of acquiring cancer by applying the extracted features as inputs to a trained artificial neural network outputting a risk classification index indicative of risk of acquiring cancer)*.

Regarding Claim 13, *Huo discloses* the system according to Claim 11, wherein the feature extraction mechanism extracts plural fractal-based features at multiple scales *(see column 9, line 60-column 10, line 8, selected texture measure derived form the mammograms of patient are then related to breast cancer risk via two different approaches . First, these measures were used to differentiate mammographic parenchymal patterns).*

Regarding claim 14*, Huo discloses* the system according to Claim 11, wherein the feature extraction mechanism extracts plural fractal-based features from an area of a region of interest of the mammogram based on a box-counting method *(see column 11, lines 3-16, the computerized method for the assessment of breast cancer risk based on the analysis of mammographic parenchymal patterns and box-counting method is well known).*

Regarding Claim 16, *Huo discloses* the system according to Claim 11, wherein the classifier mechanism comprises a linear discriminant analysis classifier (*see column 9, lines 48-59, in performing the comparison of extracted features with the model, at*

*least one of linear discriminate analysis, linear regression analysis and logistic regression analysis is performed on plural extracted features)*.

Regarding Claim 17, *Huo discloses* the system according to Claim 11, wherein the classifier mechanism comprises an artificial neural network classifier *(see column 9, lines 48-59, extracted features are merged into a measure related to the risk of acquiring cancer by applying the extracted features as inputs to a trained artificial neural network outputting a risk classification index indicative of risk of acquiring cancer)*.

Regarding Claim 20, Huo *discloses* the system according to Claim 11, wherein the feature extraction mechanism extracts from the mammogram a multi-fractal characteristic associated with the texture of the parenchyrna of the breast *(see column 9, line 60-column 10, line 8, extract features that characterize mammographic parenchymal patterns and relate to breast cancer risk would potentially benefit women seeking information regarding their individual breast cancer risk).*

Regarding Claim 21, *Huo discloses* a computer readable medium storing instructions for execution on a computer system, which when executed by the computer system, causes the computer system to perform a method for a computerized analysis of a mammogram in digital form of a breast of a patient *(see column 29, lines 20-41, CD-ROMs, floppy disk and other removable media devices)* comprising the steps of:

extracting from the mammogram at least one fractal-based feature associated with a texture of a parenchyma of the breast *(see column 9, line 60-column 10, line 8, the present invention thus involves the development of a computerized method to automatically extract features that characterized mammographic parenchymal patterns*

*and relate to breast cancer risk would potentially benefit women seeking information regarding their individual breast cancer risk)*;

applying said at least one fractal-based feature to at least one of a linear discriminant classifier*(see column 9, lines 48-59, In performing the comparison of extracted features with the model, at least one of linear discriminate analysis, linear regression analysis and logistic regression analysis is performed on plural extracted features)* and an artificial neural network classifier *(see column 9, lines 48-59, extracted features are merged into a measure related to the risk of acquiring cancer by applying the extracted features as inputs to a trained artificial neural network outputting a risk classification index indicative of risk of acquiring cancer)*; and

generating a risk marker indicative of a breast disease risk for said patient based on an output of the at least one of a linear discriminant classifier and an artificial neural network classifier*(see column 9, lines 30-59, the extracted features are compared with a predetermined model based on gene carrier information and clinical information, and a risk classification index is output as a result of the comparison)* and an artificial neural network classifier *(see column 9, lines 48-59, extracted features are merged into a measure related to the risk of acquiring cancer by applying the extracted features as inputs to a trained artificial neural network outputting a risk classification index indicative of risk of acquiring cancer)*.

Regarding Claim 23, *Huo discloses* the computer readable medium according to Claim 21, wherein the extracting step comprises:

extracting plural fractal-based features at multiple scales *(see column 9, line 60-column 10, line 8, selected texture measure derived form the mammograms of patient are then related to breast cancer risk via two different approaches . First, these measures were used to differentiate mammographic parenchymal patterns)*.

Regarding Claim 24, *Huo discloses* the computer readable medium according to Claim 21, wherein the extracting step comprises:

extracting plural fractal-based features from an area of a region of interest of the mammogram based on a box-counting method *(see column 11, lines 3-16, the computerized method for the assessment of breast cancer risk based on the analysis of mammographic parenchymal patterns and box-counting method is well known).*

Regarding Claim 26, *Huo discloses* the computer readable medium according to Claim 21, wherein the applying step comprises:

applying the features to a linear discriminant analysis classifier (*see column 9, lines 48-59, in performing the comparison of extracted features with the model, at least one of linear discriminate analysis, linear regression analysis and logistic regression analysis is performed on plural extracted feature)*.

Regarding Claim 27, *Huo discloses* the computer readable medium according to Claim 21, wherein the applying step comprises:

applying the features to an artificial neural network classifier *(see column 9, lines 48-59, extracted features are merged into a measure related to the risk of acquiring cancer by applying the extracted features as inputs to a trained artificial neural network outputting a risk classification index indicative of risk of acquiring cancer)*.

Regarding Claim 30, *Huo discloses* the computer readable medium according to Claim 21, wherein the extracting step comprises:

extracting from the mammogram a multi-fractal characteristic associated with the texture of the parenchvma of the breast *(see column 9, line 60-column 10, line 8, extract features that characterize mammographic parenchymal patterns and relate to breast cancer risk would potentially benefit women seeking information regarding their individual breast cancer risk)*.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. *Claims 5, 8, 9, 15, 18, 19, 25, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huo as applied to claims 1, 11 and 21, above in view of Caldwell ( Phys. Biol. Vol.35, No 2, 235-247, printed in the UK from IDS).*

Huo discloses extracting from the mammogram at least one fractal-based feature associated with a texture of a parenchyrna of the breast.

Huo does not disclose extracting plural fractal-based features from a volume of a region of interest of the image data mammogram based on a general Minkowski

However, Caldwell discloses regarding Claim 5, the method according to Claim 1, wherein the extracting step comprises:

extracting plural fractal-based features from a volume of a region of interest of the image data mammogram based on a general Minkowski model *(see pages 237-238, the mammograms were taken as representing three-dimensional contours, with the optical density at each point (x,y) treated as a distance measure providing the third topological dimensions and general Minkowski model is well known).*

It would have been obvious to an ordinary skill in the art at the time when the invention was made to use Caldwell's extracting plural fractal-based features from a volume of a region of interest of the image data mammogram based on a general Minkowski in Huo's extracting from the mammogram at least one fractal-based feature associated with a texture of a parenchyrna of the breast because it will allow to improve the classification performance, *[Caldwell, see page 920].*

Regarding Claim 8, *Caldwell discloses* the method according to Claim 1, wherein the extracting step comprises:

Calculating a fractal dimension from a slope (see page 238, mammogram, is related to the slope of a plot of log {A (ε)} versus log {ε}).

Regarding Claim 9, *Caldwell discloses* the method according to Claim 1, wherein the extracting step comprises:

calculating a fractal dimension from at least two slopes (see page 238, mammogram, is related to the slope of a plot of log{A(ε)} versus log{ε}).

Regarding Claim 15, *Caldwell discloses* the system according to Claim 11, wherein the feature extraction mechanism extracts plural fractal-based features from a volume of a region of interest of the mammogram based on a general Minkowski model

*(see pages 237-238, the mammograms were taken as representing three-dimensional contours, with the optical density at each point (x,y) treated as a distance measure providing the third topological dimensions and general Minkowski model is well known).*

Regarding Claim 18, *Caldwell discloses* the system according to Claim 11, wherein the feature extraction mechanism calculates a fractal dimension from a slope (see page 238, mammogram, is related to the slope of a plot of log{A(ε)} versus log{ε}).

Regarding Claim 19, *Caldwell discloses* the system according to Claim 11, wherein the feature extraction mechanism calculates a fractal dimension from at least two slopes (see page 238, mammogram, is related to the slope of a plot of log{A(ε)} versus log{ε}).

Regarding Claim 25, *Caldwell discloses* the computer readable medium according to Claim 21, wherein the extracting step comprises

extracting plural fractal-based features from a volume of a region of interest of the mammogram based on a general Minkowski model *(see pages 237-238, the mammograms were taken as representing three-dimensional contours, with the optical density at each point (x,y) treated as a distance measure providing the third topological dimensions and general Minkowski model is well known).*

Regarding Claim 28, *Caldwell discloses* the computer readable medium according to Claim 21, wherein the extracting step comprises:

calculating a fractal dimension from a slope (see page 238, mammogram, is related to the slope of a plot of log{A(ε)} versus log{ε}).

Regarding Claim 29, *Caldwell discloses* the computer readable medium according to Claim 21, wherein the extracting step comprises:

calculating a fractal dimension from at least two slopes (see page 238, mammogram, is related to the slope of a plot of log{A(ε)} versus log{ε}).

***Conclusion***

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to AKLILU k. WOLDEMARIAM whose telephone number is (571)270-3247. The examiner can normally be reached on Monday-Thursday 6:30 a.m-5:00 p.m EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Samir Ahmed can be reached on 571-272-7413. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Samir Ahmed,

Examiner
Art Unit 2624

A.W.
04/10/2008

/Samir A. Ahmed/
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